

**Response**

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Serial No.: 10/691,117

Confirmation No.: 5330

Filed: October 21, 2003

For: SULFONATED STYRENE COPOLYMERS FOR MEDICAL USES

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**Remarks**

The Office Action mailed June 3, 2009 has been received and reviewed. No claims having been added, amended, or canceled herein, the pending claims are claims 15-17, 30-32, and 34-48.

Reconsideration and withdrawal of the rejections are respectfully requested.

**Examiner Interview**

Applicants thank Patent Examiner Kristie Latrice Brooks and Supervisory Patent Examiner Johann R. Richter for granting a telephone interview with Applicants' Representative, Loren D. Albin, on September 16, 2009.

Applicants' Representative noted that the Examiner relied on Klier et al. (U.S. Patent Application Publication No. 2004/0081829) for disclosing sulfonated interpolymers, and that the Examiner further alleged that the sulfonated interpolymers disclosed by Klier et al. encompassed, for example, the sulfonated **block** copolymers recited in present independent claim 15.

Applicants' Representative disagreed, noting that Klier et al. in fact disclosed **substantially random interpolymers**, and that **substantially random** interpolymers would appear to exclude **block** copolymers. Thus, Applicants' Representative indicated his opinion that the Examiner's reliance on Klier et al. in the present rejections under 35 U.S.C. §103(a) was in error.

Upon conclusion of the interview, the Examiners indicated that upon receipt of written arguments similar to those discussed herein above, the rejection would be withdrawn and a new search would be performed. The Examiner also indicated that if the new search produced new art, then a new rejection might be issued; and if no new art was produced by the search, then the application would be allowed.

The arguments presented herein below in response to the rejections under 35 U.S.C. §103(a) are commensurate with the arguments discussed herein above.

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**Rejections under 35 U.S.C. §103(a)**

The Examiner rejected claims 15-17, 29-30, 34-46, and 48 under 35 U.S.C. §103(a) as being unpatentable over Klier et al. (U.S. Patent Application Publication No. 2004/0081829). Applicants note that claim 29 was canceled in the Amendment and Response submitted February 25, 2009. Applicants respectfully traverse the rejection of claims 15-17, 30, 34-46, and 48.

"To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." M.P.E.P. §706.02(j), quoting *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

**Claims 15-17, 30, and 34-39**

Applicants respectfully submit that the cited reference fails to expressly or impliedly suggest the invention recited in claims 15-17, 30, and 34-39, and further that the Examiner has not presented a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references, as discussed herein below.

For example, the present claims recite a method that includes, among other things, forming a water-insoluble coating including at least one salt of a polysulfonated **block copolymer** hydrogel on a porous surface. In contrast to the polysulfonated **block copolymer** hydrogels recited in the present claims, Klier et al. describes "absorbent compositions comprising sulfonated **substantially random interpolymers**" (paragraph [004], page 1; emphasis added). Thus, Applicants respectfully submit that Klier et al. fails to expressly or impliedly suggest the invention recited in claims 15-17, 30, and 34-39.

Further, Applicants respectfully submit that the polysulfonated **block copolymer** hydrogels recited in the present claims differ from the sulfonated **substantially random interpolymers** disclosed by Klier et al. to such an extent that one of skill in the art would not be motivated to modify Klier et al. by using the polysulfonated **block copolymer** hydrogels recited

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in the present claims, contrary to the allegation by the Examiner (page 5 of the Office Action mailed June 3, 2009).

For example, the present specification describes some of the surprising benefits of using polysulfonated hydrogels such as polysulfonated block copolymer hydrogels:

It has been surprisingly discovered that sulfonated styrene polymers are useful as a hydrogel material that can be used to prepare lacquers or latexes, with or without therapeutic agents, for coating onto other material substrates to yield medical articles useful for treating medical conditions. . . . These hydrogel polymers do not require chemical crosslinking, are soluble in common solvents and can be dehydrated and re-hydrated without the formation of cosmetic defects.

These sulfonated styrene polymeric hydrogels are unique, and given their superior properties relative to chemically cross-linked materials, excellent candidates for use in wound care and other medical applications for at least two very important reasons. The first is related to processing advantages that these materials possess. Sulfonated copolymer hydrogels, such as sulfonated styrene-ethylene-butylene-styrene, sulfonated styrene-ethylene and other copolymers such as sulfonated SIBS, SEPS and SIS are soluble in common organic solvents such as tetrahydrofuran, chloroform, dichloro-methane, and methyl-ethyl ketone. As such, high solids lacquers are easily prepared allowing for the casting of films, coating of articles, and impregnation of fabrics using dipping, painting, or spraying. These sulfonated hydrogels may also be processed to yield latex formulations, thus eliminating the use of organic solvents.

. . .

These sulfonated copolymer hydrogels have chemical structures that allow them to be processed from a solution/lacquer using electrodeposition or electroprocessing. Using this technique, ultrathin fibrous, high surface area device configurations may be created. Devices in the forms of sheets, tubes or other configurations including pouches or spheres may be created. The electroprocessing technique may be carried out with therapeutic agents, including biomolecules, included in the lacquer from which the polymer is spun to create drug delivering polymer strands/fibers. However, in order to fabricate sulfonated styrene

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polymer hydrogels that incorporate biomolecules, it may be necessary to hydrate the styrene copolymer hydrogel in the presence of an aqueous solution of the biomolecule of interest in order to avoid denaturation of the protein, peptide or the like. However, small, typically synthetic species such as steroids (dexamethasone), antibiotics (tetracyclines/doxycycline, gentamicin), and antineoplastic agents such as paclitaxel or sirolimus may be incorporated into the organic (solvent) solutions of the hydrogel of interest and dip coated, sprayed, painted, or electroprocessed in a straightforward manner. Furthermore, the robustness of these materials allows for them to be press-formed using high pressure into sheet, tube, and other pertinent forms.

Furthermore, these sulfonated styrene polymeric hydrogel materials do not require chemical or radiation crosslinking in order to render them with mechanical properties and characteristics suitable for them to be used in a medical application. Chemical and/or radiation crosslinkable hydrogels, such as poly (vinylpyrrolidinone) or polyethylene oxide, have poor mechanical properties even after crosslinking, thus limiting their applicability in medical articles. For example, when used as wound care materials, chemically cross-linked hydrogels are formed into sheets/films for application as a topical wound dressing product. By virtue of the poor mechanical properties of these materials, they cannot be formed into dressings with the versatility to be used as wound coverings or as wound packing(s), either as free-standing films or as gauze or fabric/material-supported configurations. (Paragraphs [0075]-[0079], pages 16-17).

In contrast to the polysulfonated **block copolymer** hydrogels recited in the present claims, Klier et al. describes "absorbent compositions comprising sulfonated **substantially random interpolymers**" (paragraph [004], page 1; emphasis added). For at least this reason, Applicants respectfully submit that Klier et al. in fact teaches away from the presently claimed invention. "[A] reference that 'teaches away' from a given combination may negate a motivation to modify the prior art to meet the claimed invention. . . . A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken

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by the applicant." *Ormco Corp. v. Align Technology Inc.*, 79 U.S.P.Q.2d 1931, 1938 (Fed. Cir. 2006).

Moreover, Applicants respectfully submit that the description by Klier et al. of the sulfonated substantially random interpolymers further differentiates the interpolymers disclosed by Klier et al. from the polysulfonated **block copolymer** hydrogels recited, for example, in present claim 15. For example, Klier et al. recite that "[t]he use of the sulfonated substantially random interpolymer-based materials for absorbent and/or superabsorbent applications" (paragraph [0015], page 2). "The term 'superabsorbent polymer' is used herein in the conventional sense in reference to polymeric materials that imbibe fluid and thereby form a swollen hydrogel. That is, a superabsorbent polymer is a hydrogel-forming polymeric gelling agent. In particular, the polymeric gelling agent comprises a substantially water-insoluble, partially neutralized, hydrogel-forming polymer material that is typically prepared from polymerizable, unsaturated, acid-containing monomers and often grafted onto other types of polymer moieties and then slightly **crosslinked** with agents such as, for example, triallyl amine." (Paragraph [0033], page 3; emphasis added).

For at least these reasons, Applicants respectfully submit that the Examiner has failed to present a convincing line of reasoning as to why the artisan would have found the invention recited in claims 15-17, 30, and 34-39 to have been obvious in light of the teachings of Klier et al.

Claims 40-46 and 48

Independent claim 40 recites a method for controlling biological organisms on a porous surface. The method includes forming a water-insoluble coating on the porous surface, wherein the water-insoluble coating includes at least one salt of a polysulfonated hydrogel that is not chemically crosslinked. Applicants respectfully submit that independent claim 40 and dependent claims 41-46 are patentable over the art of record for reasons similar to those discussed herein above for the patentability of claims 15-17, 30, and 34-39.

Independent claim 48 recites a method for controlling biological organisms on a porous surface. The method includes forming a water-insoluble coating on a porous surface that is an

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article selected from the group consisting of a garment, a gas filter, a laboratory work surface, a laboratory wipe, and a wound dressing. The water-insoluble coating includes at least one salt of at least one polysulfonated block copolymer hydrogel blended with at least one non-sulfonated polymer.

For at least the reasons discussed herein above, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness for claims 15-17, 30, 34-46, and 48 being unpatentable over Klier et al.

The Examiner rejected claims 31-32 and 47 under 35 U.S.C. §103(a) as being unpatentable over Klier et al. (U.S. Patent Application No. 2004/0081829) in view of Wood et al. (U.S. Patent No. 5,260,066). Applicants respectfully traverse the rejection.

Claims 31-32 ultimately depend from claim 15, and claim 47 ultimately depends from claim 40. The deficiencies of Klier et al. as applied to claims 15 and 40 have been discussed herein above. Further, Applicants respectfully submit that Wood et al. fail to provide that which is missing from Klier et al.

For at least this reason, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness for claim 31-32 and 47 being unpatentable over Klier et al. in view of Wood et al.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

**Power of Attorney**

Applicants submitted an executed Election, Revocation, Power of Attorney, and Request for Change of Correspondence Address document to the United States Patent and Trademark Office (USPTO) on February 25, 2009. Applicants thank the Examiner for changing the Correspondence Address of the present application to Customer Number 26813. However, the listing of the attorneys of record on the Patent Application Information Retrieval (PAIR) database of the USPTO does not reflect the above noted appointment of those registered patent

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attorneys and registered patent agents associated with Customer Number 26813. Appropriate correction is respectfully requested.

**Summary**

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

Muetting, Raasch &amp; Gebhardt, P.A.

P.O. Box 581336

Minneapolis, MN 55458-1336

Phone: (612) 305-1220

Facsimile: (612) 305-1228

**Customer Number 26813**

October 5, 2009

Date

By: 

Loren D. Albin

Reg. No. 37,763

Direct Dial (612) 305-1217

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop **Amendment**, P.O. Box 1450, Alexandria, VA 22313-1450, on this 5th day of October, 2009.

By: Name: Dani Moret

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